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October 28, 1999

Docket Management Branch (HFA - 305)
5630 Fishers lane
Room 1061
Rockville, MD 20852

Re: Docket No. 99D-4488 and 99D-4489

Dear Sirs,

We are a company devoted to applying non-chemical processing to product disinfection, disinfestation, and sterilization. The process we have developed utilizes the biocidal capabilities of energetic electrons applied to the product in the form of discrete particles supported in a swiftly moving air stream. We refer to this as the electron beam fluidized bed (ebfb). Under SBIR grants from the USDA (Dr Charles Cleland) we have been able to document the efficacy of the process in treating a wide variety of agroproducts with modest sized equipment. Our completed phase 2 effort led to the establishment of a 5 kilowatt system capable of processing 1 ton per hour at the 10kilogray dose level, a dose which has been permitted for a variety of food products in 21CFR179.26.

As members of the National Center for Food Safety and Technology in Summit-Argo, IL we were asked, in November of 1998, to help out with their Sprout Task Force activities. Through this task force, we came to know several sprout growers and the major seed merchants supplying the industry (alfalfa, radish, etc.). We felt that a central facility under close control could supply clean seed to the industry, a concept also supported by the HACCP efforts of Drs. Sizer and Slade at NCFST, with whom we have been working.

Our studies to date show that a 5 log reduction (as recommended by NACMCF) in the non-pathogenic surrogate (K12) for E. coli 0157:H7, used in these studies, can be achieved with little effect on germination. There should be no expected effect on nutritional content of the sprouts although further nutritional studies are required (and planned at NCFST).

We have submitted a phase 1 proposal to the USDA for this work, jointly with NCFST, in order to carry this through the R&D required for petitioning the USFDA for its application in this industry. Some of these requirements may be satisfied upon approval of a petition to FDA, currently under review, submitted by the Food Irradiation Coalition to allow use of irradiation on a variety of ready-to-eat foods, including alfalfa seeds used for growth of edible sprouts (August 1999).

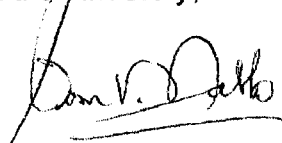
99D-4488

C1

Indeed, we would like to accelerate these studies as we feel our ebfb system provides a centralized, well controlled, non-invasive, physical process to help control one area of major concern (seed contamination) in this industry... an industry which, as you know, is suffering badly form recent advisories and press coverage.

We are encouraged by the Administration's Food Safety Initiative, and wanted to draw your attention to this work which can play an important role in restoring consumer confidence in these valuable food products.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Sam V. Nablo", written over a horizontal line.

Sam V. Nablo, Ph.D.
President

cc: NCFST: Dr. C. Sizer
USDA/SBIR: Dr. C. Cleland

HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CROSS REFERENCE SHEET

Docket Number/Item Code: 99D-4488/C1

See Docket Number/Item Code: 99D-4489/C1

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